

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS**

SEP 25 2012

**1. Applicant**

Quality Electrodynamics, LLC. (QED)  
700 Beta Drive, Suite 100  
Mayfield Village, OH 44143  
Phone (440) 484-2228

**2. Contact**

Kathleen Aras  
Director, Regulatory and Quality Affairs

**3. Date prepared:**

August 27, 2012

**4. Tradename**

Toshiba 3T 32CH Head SPEEDER Coil

**5. Common name**

Coil, magnetic resonance, specialty

**6. Classification**

21 CFR 892.1000

**7. Equivalent Device**

Trade name	Legally marketed predicate device	Manufacturer
Toshiba 3T 32CH Head SPEEDER Coil	1.5T Atlas SPEEDER Head-Neck Coil	Quality Electrodynamics

**8. Device Description**

The Toshiba 3T 32CH Head SPEEDER Coil is designed for use with a Vantage Titan 3T System, manufactured by Toshiba Medical Systems Corporation.

**9. Indications for Use**

The Toshiba 3T 32CH Head SPEEDER Coil is intended for use with the Toshiba Vantage Titan 3T MRI system to produce diagnostic images of the head that can be interpreted by a trained physician.

**510(k) SUMMARY OF SAFETY AND EFFECTIVENESS****10. Comparison with Predicate Devices**

<b>510(k) #</b>	<b>Legally marketed predicate device</b>	<b>Manufacturer</b>
K083160	1.5T Atlas SPEEDER Head-Neck Coil	Quality Electrodynamics

The Toshiba 3T 32CH Head SPEEDER Coil in this submission and the 1.5T Atlas SPEEDER Head-Neck Coil described in K083160 are both phased-array, receive-only coils. The main differences are that the Toshiba 3T 32CH Head SPEEDER Coil has a higher channel count (32 vs. 15), fewer anterior attachments (2 vs. 4) and is designed for use with a 3T system as opposed to a 1.5T system compared to the predicate coil.

**11. Non-Clinical Tests**

The Toshiba 3T 32CH Head SPEEDER Coil was tested to and found to be compliant with IEC 60601-1, Medical electrical equipment - Part 1: General requirements for basic safety and essential performance, second and third editions.

The signal-to-noise ratio (SNR) was measured according to NEMA MS 9-2008, Characterization of Phased Array Coils for Diagnostic Magnetic Resonance Images.

Image Uniformity was assessed in accordance with NEMA MS-3 2008, Determination of Image Uniformity in Diagnostic Magnetic Resonance Images.

**12. Conclusion**

It is the opinion of Quality Electrodynamics that the Toshiba 3T 32CH Head SPEEDER Coil is substantially equivalent to the above-listed legally marketed predicate devices. Use of the Quality Electrodynamics coil does not result in any new potential hazards.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room – WO66-G609  
Silver Spring, MD 20993-0002

Ms. Kathleen Aras  
Director, Regulatory and Quality Affairs  
Quality Electrodynamics, LLC  
700 Beta Drive, Suite 100  
MAYFIELD VILLAGE OH 44143

SEP 25 2012

Re: K122638

Trade/Device Name: Toshiba 3T 32 CH Head SPEEDER Coil  
Regulation Number: 21 CFR 892.1000  
Regulation Name: Magnetic resonance diagnostic device  
Regulatory Class: II  
Product Code: MOS  
Dated: August 27, 2012  
Received: August 29, 2012

Dear Ms. Aras:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into class II (Special Controls), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

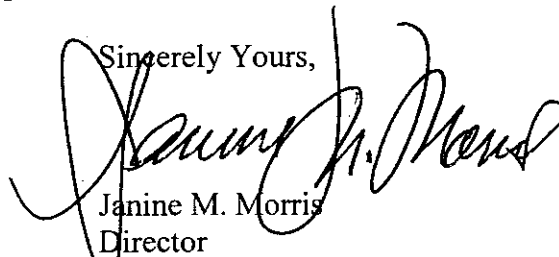
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); medical device reporting (reporting of

medical device-related adverse events) (21 CFR 803); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820). This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostic Device Evaluation and Safety at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely Yours,

A handwritten signature in black ink, appearing to read "Janine M. Morris", is written over the typed name and title.

Janine M. Morris  
Director

Division of Radiological Devices  
Office of In Vitro Diagnostic Device  
Evaluation and Safety  
Center for Devices and Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K122638

Device Name:

Toshiba 3T 32CH Head SPEEDER Coil

Indications for Use:

The Toshiba 3T 32CH Head SPEEDER Coil is intended for use with the Toshiba Vantage Titan 3T MRI system to produce diagnostic images of the head that can be interpreted by a trained physician.

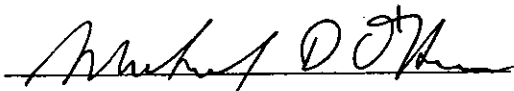
Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF  
NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)



Division Sign-Off  
Office of In Vitro Diagnostic Device  
Evaluation and Safety

K122638